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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,306	06/05/2006	Martin Schymura	08146.0011U1	6442
23859 7590 04/28/2009 Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER GWARTNEY, ELIZABETH A	
			ART UNIT 1794	PAPER NUMBER
			MAIL DATE 04/28/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,306

Applicant(s)

SCHYMURA, MARTIN

Examiner

Elizabeth Gwartney

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02/11/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The Amendment filed 02/11/2009 has been entered. Claims 18, 22, 29 and 32 have been amended and claims 19 and 28 have been cancelled. Claims 18, 20-27 and 29-32 remain pending.
2. The previous 112 2nd Paragraph and Use Claim rejections have been withdrawn in light of applicant's amendments made 02/11/2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 18, 20-27 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 18, the recitation "wherein L-carnitine comprises a crystalline tartrate having the formula $C_{18}H_{36}N_2O_{12}$ and having a molecular mass of 472.49 u." renders the claim indefinite. Claim 18 is directed to a fruit gum composition comprising L-carnitine in a form which is at least sometimes crystalline, having the formula $C_7H_{15}NO_3$ or $C_{18}H_{36}N_2O_{12}$, at least one L-carnitine complex, at least one L-carnitine complex salt, at least one mixture of substances containing L-carnitine, at least one L-carnitine fumarate or any combination thereof. It is not clear how the fruit gum composition can comprise L-carnitine having the formula $C_7H_{15}NO_3$ given the

amendment which narrows the limitation to include only a L-carnitine of the formula $C_{18}H_{36}N_2O_{12}$.

Regarding claim 29, the recitation “and further L-carnitine as a crystalline tartrate having the formula $C_{18}H_{36}N_2O_{12}$ ” renders the claim indefinite because it further limits the already recited limitation wherein at least one of L-carnitine in crystalline form, having a formula of $C_7H_{15}NO_3$ or $C_{18}H_{36}N_2O_{12}$. Thus, it is not clear if L-carnitine of formula $C_7H_{15}NO_3$ would meet the limitations of the claim.

Regarding claim 32, the recitation “further comprising the use of the fruit gum composition for the manufacture of food supplements” renders the claim indefinite because it is not clear how this limitation further limits the method of claim 29 given that fruit gum comprising L-carnitine is inherently a supplement.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 18, 20-27, 29-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 6,077,557) in view of Kohl et al. (US 5,073,376) and Food Chemicals Codex "Carnauba Wax", and "Beeswax, White".

Regarding claims 18 and 20-21, Gordon et al. disclose an intermediate moisture sweetened gelled food, i.e. fruit snacks, composition comprising nutritive carbohydrate sweeteners, gelling agents, acidulants, flavoring, coloring agents (Abstract, C1/L27-28, C6/L49-63, C9/L31-60) and a coating of sugar or oil and wax (C14/L25-46)

While Gordon et al. disclose fruit snacks supplemented with calcium (Abstract), the reference does not disclose that the fruit snacks additionally comprise a crystalline tartrate form of L-carnitine having the formula $C_{18}H_{36}N_2O_{12}$ and having a molecular mass of 472.49 u.

Kohl et al. disclose peppermint and orange flavored sucking tablets that comprise L-carnitine-L-tartrate (Abstract, C2-3/Example 2, C3-4/Example 3). Kohl et al. disclose that L-carnitine is widely use in food for athletes because it contributes significantly to supplying the muscles with energy and promotes endurance performance (C1/L10-22). Kohl et al. disclose that tablets comprising L-carnitine as a crystalline tartrate form exhibit less hygroscopicity, longer stability and better capacity for being stored (Abstract).

Given that Kohl et al. teach L-carnitine-L-tartrate identical to that presently claimed, it is clear that it would intrinsically have a formula of $C_{18}H_{36}N_2O_{12}$ and a molecular mass of 472.49 u.

Gordon et al. and Kohl et al. are combinable because they are concerned with the same field of endeavor namely, nutritionally supplemented confectionary products. It would have

been obvious to one of ordinary skill in the art at the time the invention was made to have added L-carnitine-L-tartrate, as taught by Kohl et al., to the fruit snacks of Gordon et al. because L-carnitine improves muscle activity and brings about an increase in endurance and stress tolerance as well as delayed fatigue and shortened recover time (C1/L10-22). Further, by using L-carnitine-L-tartrate, the products will exhibit less hygroscopicity, longer stability and better capacity for being stored (Abstract).

Regarding claim 22, modified Gordon et al. disclose all of the claim limitations including that the fruit snack composition comprises an L-carnitine in a form which is at least sometimes crystalline, having the formula $C_7H_{15}NO_3$. Given that modified Gordon et al. disclose a L-carnitine-L-tartrate, the limitations of claim 22 have been met.

Regarding claims 23-25, modified Gordon et al. disclose all of the claim limitations as set forth above. Further, Gordon et al. disclose that the sweetener is selected from the group consisting of sucrose, fructose, or mixtures thereof (C4/L46-57); the gelatinizer comprises gelatin, pectin, starch, or mixtures thereof (C6/L49-63); and the souring agent comprises citric acid, malic acid, or mixtures thereof (C10/L4-5).

Regarding claim 26, modified Gordon et al. disclose all of the claim limitations as set forth above. Given that Gordon et al. disclose coloring agents broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any coloring agent, including fruit or plant extract, artificial color or nature-identical colorant, to arrive at the current invention. Further, given that Gordon et al. disclose composition including color, it is clear that the color would intrinsically have to be either one of artificial or nature-identical.

Regarding claim 27, modified Gordon et al. disclose all of the claim limitations as set forth above. Gordon et al. also disclose that the release and glazing agent comprises wax and a liquid oil (C14/L28-32). While Gordon et al. discloses wax, the reference does not explicitly disclose beeswax or carnauba wax. However, y Food Chemicals Codex teaches that it was well known to use white beeswax and carnauba wax as glazing agents (Function). Given that Gordon et al. disclose wax broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used any food wax, including white beeswax or carnauba wax, to arrive at the current invention.

Regarding claims 29-30, Gordon et al. disclose a method of making an intermediate moisture sweetened gelled food, i.e. fruit snacks, composition comprising nutritive carbohydrate sweeteners, gelling agents, acidulants, flavoring, coloring agents (Abstract, C1/L27-28, C6/L49-63, C9/L31-60) and a coating of sugar or oil and wax (C14/L25-46)

While Gordon et al. disclose fruit snacks supplemented with calcium (Abstract), the reference does not disclose that the fruit snacks additionally comprise a crystalline tartrate form of L-carnitine having the formula $C_{18}H_{36}N_2O_{12}$ and having a molecular mass of 472.49 u.

Kohl et al. disclose peppermint and orange flavored sucking tablets that comprise L-carnitine-L-tartrate (Abstract, C2-3/Example 2, C3-4/Example 3). Kohl et al. disclose that L-carnitine is widely use in food for athletes because it contributes significantly to supplying the muscles with energy and promotes endurance performance (C1/L10-22). Kohl et al. disclose that tablets comprising L-carnitine as a crystalline tartrate form exhibit less hygroscopicity, longer stability and better capacity for being stored (Abstract).

Given that Kohl et al. teach L-carnitine-L-tartrate identical to that presently claimed, it is clear that it would intrinsically have a formula of $C_{18}H_{36}N_2O_{12}$ and a molecular mass of 472.49 u.

Gordon et al. and Kohl et al. are combinable because they are concerned with the same field of endeavor namely, nutritionally supplemented confectionary products. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added L-carnitine-L-tartrate, as taught by Kohl et al., to the fruit snacks of Gordon et al. because L-carnitine improves muscle activity and brings about an increase in endurance and stress tolerance as well as delayed fatigue and shortened recover time (C1/L10-22). Further, by using L-carnitine-L-tartrate, the products will exhibit less hygroscopicity, longer stability and better capacity for being stored (Abstract).

Regarding claim 32, modified Gordon et al. disclose all of the claim limitations as set forth above. Gordon et al. also disclose a fruit snack supplemented with calcium (i.e. food supplement).

Further, statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art or process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old product

patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

8. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 6,077,557) in view of Engel et al. (US 5,976,550) and Food Chemicals Codex ("L-Carnitine").

Regarding claims 29 and 31, Gordon et al. disclose a method of making an intermediate moisture sweetened gelled food, i.e. fruit snacks, composition comprising nutritive carbohydrate sweeteners, gelling agents, acidulants, flavoring, coloring agents (Abstract, C1/L27-28, C6/L49-63, C9/L31-60) and a coating of sugar or oil and wax (C14/L25-46)

While Gordon et al. disclose fruit snacks supplemented with calcium (Abstract), the reference does not disclose that L-carnitine in pure crystalline form having a degree of purity of 99% and not more than 1% of residual components is added to the fruit snack composition.

Engel et al. teach a sugar based confectionary containing therapeutic amounts of L-carnitine (Abstract). Engel et al. teach that L-carnitine is a fat metabolizing nutraceutical that helps burn whatever fat the body does consume.

Food Chemicals Codex teaches that L-carnitine occurs as white crystals, has the formula weight $C_7H_{15}NO_3$, and has a molecular mass of 161.20 (p.1/Formula, Description). Given that Engel et al. teach L-carnitine, it is clear that the L-carnitine would intrinsically possess the recited properties. Further, given that Engel et al. teach L-carnitine broadly, absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art at the time of the

invention to have used any L-carnitine including the pure crystalline form, to arrive at the current invention.

Gordon et al. and Engel et al. are combinable because they are concerned with the same field of endeavor namely, nutritionally supplemented confectionary products. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added L-carnitine, as taught by Engel et al, to the fruit snacks of Gordon et al. for the purpose of metabolizing fat and contributing to weight loss.

Response to Arguments

9. Applicant's arguments with respect to claims 18-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794